PATENT COOPERATION TREATY

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILIT (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

YREC'D	Ĺ	1	CEP	2005
WIPO			-in	POT.

Applicant's or agent's file reference	FOR FURTHER ACTION		See Form PCT/IPEA/416					
SHP026.4.1A								
International application No.	International filing date (a	lay/month/year)	Priority date (day/month/year)					
PCT/US04/39400			25 November 2003 (25.11.2003)					
International Patent Classification (IPC) or national classification and IPC								
IPC(7): A61M 5/00 and US Cl.: 604/263								
Applicant								
SPECIALIZED HEALTH PRODUCTS, INC.								
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.								
2. This REPORT consists of a total of sheets, including this cover sheet.								
3. This report is also accompanied by ANNEXES, comprising:								
a. (sent to the applica	a. (sent to the applicant and to the International Bureau) a total of sheets, as follows:							
sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).								
sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.								
b. (sent to ti	he International Bureau	only) a total of (in	idicate type and number of electronic					
carrier(s))	44							
, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).								
4. This report contains indica	ations relating to the follo	wing items:						
Box No. I Basis of the report								
Box No. II Pr	Priority							
	Lack of unity of invention							
	easoned statement under Article 35(2) with regard to novelty, inventive step or dustrial applicability; citations and explanations supporting such statement							
<u> </u>	ertain documents cited							
Box No. VII C	ertain defects in the international application							
Box No. VIII C	ertain observations on the international application							
Date of submission of the demand		Date of completion of this report						
02 June 2005 (02.06.2005)		21 July 2005 (21.07.2005)						
Name and mailing address of the IPEA/	US	Authorized officer						
Mail Stop PCT, Attn: IPEA/US Commissioner for Patents		Cris L. Rodriguez	Diam Smith					
P.O. Box 1450 Alexandria, Virginia 22313-1450			\mathcal{F}					
Facsimile No. (703) 305-3230		Telephone No. 571-272-4964						

Form PCT/IPEA/409 (cover sheet)(January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/39400

Box No. I Basis of the report							
1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.							
This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:							
international search (under Rules 12.3 and 23.1(b))							
publication of the international application (under Rule 12.4)							
international preliminary examination (under Rules 55.2 and/or 55.3)							
2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):							
the international application as originally filed/furnished							
the description:							
pages 1-33 as originally filed/furnished							
pages* NONE received by this Authority on							
pages* NONE received by this Authority on							
the claims:							
pages 34-36 as originally filed/furnished							
pages* NONE as amended (together with any statement) under Article 19							
pages* NONE received by this Authority on							
pages* NONE received by this Authority on							
the drawings:							
pages 1-93 as originally filed/furnished							
pages* NONE received by this Authority on							
pages* NONE received by this Authority on							
a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.							
3. The amendments have resulted in the cancellation of:							
the description, pages							
the claims, Nos							
the drawings, sheets/figs							
the sequence listing (specify):							
any table(s) related to the sequence listing (specify):							
This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).							
the description, pages							
the claims, Nos.							
the drawings, sheets/figs							
the sequence listing (specify):							
any table(s) related to the sequence listing (specify):							
* If item 4 applies, some or all of those sheets may be marked "superseded."							
Form PCT/IPEA/409 (Box No. I) (January 2004)							

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

Form PCT/IPEA/409 (Box No. V) (January 2004)

International application No. PCT/US04/39400

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement								
1. Statement								
Novelty (N)	Claims	1-27	YES					
• • •		NONE						
Inventive Step (IS)	Claims		YES					
	Claims	NONE	NO					
Industrial Applicability (IA)	Claims	1-27	YES					
		NONE	NO NO					
2. Citations and Explanations (Rule 70.7) Claims 1-27 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a medical needle with a reset surface. Claims 1-27 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry. NEW CITATIONS NEW CITATIONS NEW CITATIONS								